AUG - 5 2011

K111762

Abbreviated 510(k) Summary

ST AIA-PACK ACTH

Date:	**June 17, 2011**
Submitter:	**Tosoh Bioscience, Inc** **3600 Gantz Road** **Grove City, OH 43123**
Contact Person:	**Judith K. Ogden** **Director, New Business & Technical Development** **6000 Shoreline Ct., Ste. 101** **South San Francisco, CA 94080** **Phone: 650-636-8112** **Fax: 650-636-8113** **Email: Judy.Ogden@tosoh.com**
Device Name:	**ST AIA-PACK DHEA-S Calibrator Set**
Classification	**Class II** **JIT** **Clinical Chemistry** **21 CFR 862.1150**
Predicate Device:	**k040181** **Access DHEA-S Calibrators**

Abbreviated 510(k) Summary

ST AIA-PACK ACTH

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Device Description:

The ST AIA-PACK DHEA-S CALIBRATOR SET contains human sera with assigned levels of DHEA-S. Calibration should be performed according to the schedule indicated in the TOSOH AIA System Operator's Manual.

2 x 1 mL		
ST AIA-PACK DHEA-S CALIBRATOR (1)	0	µg/dL

Human serum containing no detectable concentration of DHEA-S with sodium azide as a preservative.

2 x 1 mL		
ST AIA-PACK DHEA-S CALIBRATOR (2)	5.0	µg/dL
(approx.)		
ST AIA-PACK DHEA-S CALIBRATOR (3)	12	µg/dL
(approx.)		
ST AIA-PACK DHEA-S CALIBRATOR (4)	60	µg/dL
(approx.)		
ST AIA-PACK DHEA-S CALIBRATOR (5)	300	µg/dL
(approx.)		
ST AIA-PACK DHEA-S CALIBRATOR (6)	1200	µg/dL
(approx.)		

Human serum containing the assigned concentration of DHEA-S (described on each vial) with sodium azide as a preservative.

ST AIA-PACK ACTH Calibrator Set P/N 025322

Device Intended Use:

The ST AIA-PACK DHEA-S CALIBRATOR SET is intended for IN VITRO DIAGNOSTIC USE ONLY for the calibration of the ST AIA-PACK DHEA-S assay.

Substantial Equivalence:

Comparison between the Tosoh ST AIA-PACK DHEA-S Calibrator Set and the Access DHEA-S Calibrators

Characteristic	**Predicate** **Access® DHEA-S Calibrators (K040181)**	**Tosoh ST AIA-PACK DHEA-S Calibrator Set**
Intended Use	The Access DHEA-S Calibrators are intended to calibrate the Access DHEA-S assay for the quantitative determination of Dehydroepiandrosterone sulphate levels in human serum and plasma using the Access Immunoassay Systems	The ST AIA-PACK DHEA-S CALIBRATOR SET is intended for IN VITRO DIAGNOSTIC USE ONLY for the calibration of the ST AIA-PACK DHEA-S assay.
Analyte	DHEA-S	DHEA-S
Analyzer	Beckman Coulter Access Immunoassay System	Tosoh AIA Systems
Levels	Six (0, 20, 50, 200, 500 and 1000 µg/mL approximately)	Six (0, 5, 12, 60, 300 and 1200 µg/mL, approximately)
Format	Ready to use liquid calibrators; Six two-mL bottles, one for each of the six calibrator levels.	Ready to use liquid calibrators; Six one-mL bottles, one for each of the six calibrator levels.
Assay Protocol	Competitive immunoenzymatic	Same
Chemistry	Bovine serum / buffer base with surfactant and preservative	Human serum base with sodium azide preservative

Traceability	Traceable to the manufacturer's working calibrators.	Same
Matrix	Serum Plasma	Serum Heparinized plasma EDTA plasma Citrated plasma cannot be used
Storage	Store in upright and refrigerate at 2 to10°C.	Store in upright position at 2-8°C when not in use.
Stability (un-opened vial)	Stable until the expiration date stated on the label when stored at 2 to10°C.	When stored unopened and refrigerated at 2-8°C, the calibrator set is stable until the expiration date on the label.
Stability (opened vial)	Vial is stable at 2 to10°C for 28 days after initial use.	The calibrator materials should be used within 1 day of opening, provided the vials are kept tightly sealed and refrigerated at 2-8°C.
Shelf-life	12 months when stored unopened and refrigerated at 2-8°C	12 months when stored unopened and refrigerated at 2-8°C
Calibration Stability	Assay calibration data are valid up to 28 days	Stable up to 90 days

Conclusion:

The Tosoh Bioscience, Inc. ST AIA-PACK DHEA-S Calibrator Set is substantially equivalent to the Access DHEA-S Calibrators k040181 for the in vitro diagnostic use only for the calibration the ST AIA-PACK DHEA-S assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Tosoh Bioscience, Inc
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South San Francisco, CA 94080

AUG 0 5 2011

Re: k111762
Trade Name: ST AIA-PACK DHEA-S Calibrator Set
Regulation Number: 21 CFR §862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Codes: JIT
Dated: June 22, 2011
Received: June 23, 2011

Dear Ms. Ogden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k 111762

Device Name: ST AIA-PACK DHEA-S Calibrator Set

Indication For Use: ST AIA-PACK DHEA-S Calibrator Set is designed for IN VITRO DIAGNOSTIC USE ONLY for the calibration of the ST AIA-PACK DHEA-S assay on Tosoh AIA System Analyzers

Prescription Use __√__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

K111762